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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,389	02/05/2007	David M. Hampson	82047001/P3138-US	5991
2500.5 7590 02/17/2011 Intellectual Property Dept.			EXAMINER	
Dewitt Ross & Stevens SC			STUART, COLIN W	
2 East Mifflin Suite 600	Street		ART UNIT	PAPER NUMBER
Madison, WI 53703-2865			3771	
			NOTIFICATION DATE	DELIVERY MODE
			02/17/2011	ELECTRONIC

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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docket-ip@dewittross.com

# Office Action Summary

Application No.	Applicant(s)	
10/596,389	HAMPSON ET AL.	
Examiner	Art Unit	
COLIN STUART	3771	

	COLIN STUART	3771	
The MAILING DATE of this communication appe Period for Reply	ears on the cover sheet with the c	correspondence ad	dress
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 OFR 1.13  after SIX (f) MCNT15 from the mailing date of this communication.  - Failur to really writin the act or extended profit of reply will, by statute,  Any reply received by the Office later than three months after the mailing  arrand pattern term adjustment. See 37 OFR 1.794(b).	TE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be tin Ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this or D (35 U.S.C. § 133).	
Status			
1) Responsive to communication(s) filed on 16 Ju 2a) This action is FINAL. 2b) This 3) Since this application is in condition for allowan closed in accordance with the practice under E.	action is non-final. ce except for formal matters, pro		merits is
Disposition of Claims			
4) ⊠ Claim(s) 11.12.14.15.17-25 and 27-31 is/are pe 4a) Of the above claim(s) is/are withdraw 5) □ Claim(s) is/are allowed. 6) ☒ Claim(s) 11.12.14.15.17-25 and 27-31 is/are re 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or	n from consideration.		
Application Papers			
9) ☐ The specification is objected to by the Examiner  10) ☑ The drawing(s) filed on 12 June 2006 is/are: a)  Applicant may not request that any objection to the c  Replacement drawing sheet(s) including the correction  11) ☐ The oath or declaration is objected to by the Examination	☐ accepted or b) ☐ objected to Irawing(s) be held in abeyance. Sec on is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CF	
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign   a) All b) Some c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priori	have been received. have been received in Applicati ty documents have been receive (PCT Rule 17.2(a)).	on No ed in this National	Stage
Attachment(s)			
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1) Notice of References Cited (PTO-892)	4)
2) Dilydre of Oreffsperson's Palent Oreson's Severa (PTO-948)	77.7

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date \_\_\_\_\_\_.

4)		Interview Summary (PTO-413) Paper No(s)/Mall Date
<b>5</b> \	П	Notice of Informal Patent Applies

5) Notice of 6) Other:

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#### DETAILED ACTION

1. This office action is in response to the request for continued examination and amendments filed 6/16/10. As directed by the amendment: claims 11, 19, 21, 25, and 27 have been amended, claims 30-31 have been added, and claims 13, 16, and 26 have been cancelled. As such, claims 11-12, 14-15, 17-25, and 27-31 are pending in the instant application.

## Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the heating elements must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

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application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

## Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-12, 14-15, and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 11, the language "joined areas of the facing surfaces being situated about the inflatable bladder" (line 14) is unclear because it appears the applicant is redefining the locations of the joined areas of the facing surfaces from about the peripheral edges (line 6-7) of the inner and outer sheets to being about the inflatable bladder and it is not clear to the examiner the intended location of the joined areas of the inner and outer sheets.

In regards to claim 18, the claimed range of bladder pressure being "no greater than approximately 60mmHg" (line 2) is unclear because the examiner cannot ascertain the intended upper bound of the pressure range.

Claims 12, 14-15 and 17 are rejected based upon dependency to a rejected claim.

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#### Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25 and 27-30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In regards to claim 25, the language "the inflatable bladder being situated along the circumference of the limb" (line 6-7) appears to be claiming the human body, or a portion of the human body, which is non-statutory subject matter. The examiner suggests amending to read —the inflatable bladder adapted to be situated along the circumference of the limb--.

Claims 27-30 are rejected based upon dependency to a rejected claim.

#### Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this till, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

 Claims 11-12, 19, 22-24, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuiper et al. (2003/0191420) in view of Zablotsky et al. (5,450,858).

In regards to claim 11, Kuiper teaches a an inflatable compression device which includes an inextensible outer sheet (22 Fig. 3; see also para. 0060); and an inner sheet 24 extending at least substantially parallel to the outer sheet (see Fig. 3) wherein the inner and outer sheet include facing surfaces situated directly adjacent each other (see Fig. 3) and being bounded by peripheral edges (Fig. 3), the facing surfaces having joined areas (see Fig. 3 at 48) extending at least about their peripheral edges (joined areas also at peripheral at 28 Fig. 3), with the facing surfaces being separated adjacent the joined areas (see Fig. 3, the joined areas 48 define bladders which are inflatable space where the facing surfaces of inner and outer sheets are separated); and inflatable bladder (26 Fig. 3). Kuiper is silent as to the inflatable bladder being a separate element which is situated between the inner and outer sheets with the bladder being physically joined to the facing surface of the outer sheet and not being physically joined to the facing surface of the inner sheet. However, Zablotsky teaches a similar inflatable compression device which includes an inner and outer sheet (Zablotsky 86 & 84 Fig. 9,

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respectively) in which an inflatable bladder (Zablotsky 116 Fig. 9) in which the inflatable bladder is physically joined to the facing surface of the outer sheet and not physically joined to the facing surface of the inner sheet (see Zablotsky Fig. 9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Kuiper device by replacing the bladder defined by the inner and outer sheets with the removable inflatable bladder physically attached to the outer sheet and not physically attached to the inner sheet as taught by Zablotsky in order to provide removability for the inflatable bladders for replacement or varying the configuration of the inflatable bladders in the compression device for enhanced therapeutic effects. The now modified Kuiper device's joined areas of the facing surfaces are situated about the inflatable bladder (see Zablotsky Fig. 9 and Kuiper Fig. 3).

In regards to claim 12, the modified Kuiper device's inflatable bladder is spaced away from at least a portion of the joined areas (see Zablotsky Fig. 9).

In regards to claim 19, Kuiper shows an inflatable compression device including flexible inner and outer sheets (Kuiper 24 and 22, respectively; note that while outer sheet 22 is disclosed as inextensible in para. 0060, it is flexible as to wrap around and conform to a limb of a user) having adjacent facing surfaces (see Kuiper Fig. 3), with the facing surfaces of each sheet defining at least a major portion of the sheet's area (see Fig. 3 Kuiper); and peripheral edges bounding the facing surfaces, wherein the inner and outer sheets are joined at least at the peripheral edges (see Kuiper Fig. 3 at 48; joined areas also at peripheral at 28 Fig. 3) and a noninflatable area (Kuiper at 48 Fig. 3) wherein the facing surfaces of the inner and outer sheets are adjacently situated (see

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Kuiper Fig. 3). Kuiper is silent as to including an inflatable area including an inflatable bladder directly between the inner and outer sheets with the bladder being physically joined to the outer sheet and not being physically joined to the inner sheet. However, Zablotsky teaches a similar inflatable compression device which includes an inner and outer sheet (Zablotsky 86 & 84 Fig. 9, respectively) in which an inflatable bladder (Zablotsky 116 Fig. 9) in which the inflatable bladder is physically joined to the facing surface of the outer sheet and not physically joined to the facing surface of the inner sheet (see Zablotsky Fig. 9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Kuiper device by replacing the bladder defined by the inner and outer sheets with the removable inflatable bladder physically attached to the outer sheet and not physically attached to the inner sheet as taught by Zablotsky in order to provide removability for the inflatable bladders for replacement or varying the configuration of the inflatable bladders in the compression device for enhanced therapeutic effects.

In regards to claims 22-23, the modified Kuiper device includes a noninflatable area which includes a flap having a fastener thereon (see Kuiper zipper 30 at noninflatable area of Fig. 3; see also Fig. 7 of Zablotsky). Note that the zipper includes multiple fasteners (the multiple interlocking teeth of the zipper itself) and therefore teach bearing multiple fasteners such that the compression device is defined by a closed loop bearing the inflatable area and the joined noninflatable areas. However, in the event that the zipper is considered to be a single fastener, one of ordinary skill in the art at the time the invention was made would have also found it obvious to substitute the single

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zipper of the modified Kuiper device with the obvious variant of a plurality of snap buttons as one would expect the modified Kuiper device to perform equally well with a plurality of snap buttons.

In regards to claim 24, the modified Kuiper device's outer sheet is formed of inextensible material (see Kuiper para. 0060 and para. 0066).

In regards to claim 31, the modified Kuiper device includes one or more locations at which the outer sheet is joined to the bladder spaced away from locations at which the outer sheet is joined to the inner sheet (see Zablotsky Fig. 9).

 Claims 14-15 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuiper et al. (2003/0191420) and Zablotsky et al. (5,450,858) as applied to claims 11 or 19 above, and further in view of Detty et al. (5,766,236).

In regards to claims 14-15, the modified Kuiper device teaches all the limitations as discussed above, but is silent as to including heating elements on or within the inner sheet and wherein the entirety of the inner sheet is heated. However, Detty teaches a compression sleeve device (see Detty col. 2 In. 15-19) which includes heating elements (Detty 42 with electrode 24 Fig. 2 and 5) which heats the entirety of the inner sheet (see Detty col. 5 In. 42-44). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Kuiper device to include heating elements as taught by Detty in order to provide an additional therapeutic effect to the user.

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In regards to claims 20-21, the modified Kuiper device teaches all the limitations as discussed above, but is silent as to at least a substantial portion of the inner sheet defines a heating element, which includes electrically conductive material. However, Detty teaches a compression sleeve device (see Detty col. 2 In. 15-19) which includes a heating element which is at least a substantial portion of the inner sheet and is electrically conductive material (Detty 42; see also Detty col. 5 In. 42-44 and col. 4 In. 53-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Kuiper device to include the heating elements as taught by Detty in order to provide an additional therapeutic effect to the user.

 Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuiper et al. (2003/0191420) and Zablotsky et al. (5,450,858) as applied to claim 11 above, and further in view of Arkans (6,007,559).

In regards to claim 17, the modified Kuiper device teaches all the limitations as discussed above, but is silent as to including a pump which cyclically provides gas to and removes gas from the bladder in the repeated steps of providing gas to the bladder for up to 2/10 of a minute; and subsequently removing at least some of the gas from the bladder for the remainder of the minute. However, Arkans teaches a cyclical pump for providing gas to a bladder for about 3 seconds (Arkans col. 11, In. 25-28) and removing gas from the bladder (col. 11, In. 25-28) and gas from the bladder for the up to a minute (col. 11, In. 25-28). Therefore, it would have been obvious to one of ordinary skill in the

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art at the time the invention was made to modify the modified Kuiper device to include a cyclical pump to provide a specific inflation and inflation cycle, as taught by Arkans, for the purpose of providing an appropriate therapy for a patient (Arkans col. 11, In. 18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide gas for 2/10 of a minute, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art, and it appears that the modified Kuiper device would perform equally as well with an extended inflation period. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

In regards to claim 18, the modified Kuiper pump as modified above in claim 17, is silent regarding that it provides a pressure of no greater than approximately 60 mmHg. However, Arkans teaches providing a pressure of 45 mmHg. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kuiper's pump pressure to no greater than approximately 60 mmHg, as taught by Arkans, for the purpose of providing the appropriate therapy for the patient. Although Arkans teaches a range of pressure provided to the patient higher and lower than 60 mmHg, discovering an optimum value of a result effective variable involves only routine skill in the art, and it appears that providing a pressure of no greater than 60 mmHg would work effectively using Kuiper's modified pump. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

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 Claims 25 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuiper et al. (2003/0191420) in view of Zablotsky et al. (5,450,858) and Detty et al. (5,766,236).

In regards to claim 25. Kuiper shows an inflatable compression device including at least substantially planar flexible body (see Fig. 1-2; note that the body is flexible as to conform to the circumference of a user's limb and is planar when in the flat unwrapped state), the body including an inflatable bladder 26, and noninflatable portions (see Fig. 3 at 48 and 28) located at least on opposite sides of the inflatable bladder, the noninflatable portions bearing fasteners (zipper 30 which includes multiple interlocking teeth) whereby the noninflatable portions are configured to be fastened together about the circumference of a limb with the inflatable bladder being situated along the circumference of the limb (see Fig. 4). Note that in the event that the zipper is considered to be a single fastener, one of ordinary skill in the art at the time the invention was made would have also found it obvious to substitute the single zipper of the modified Kuiper device with the obvious variant of a plurality of snap buttons as one would expect the modified Kuiper device to perform equally well with a plurality of snap buttons. Kuiper's body is formed of joined inner 24 and outer 22 sheets, the sheets being situated directly adjacent each other (see Fig. 3; directly adjacent at locations 48 and at location 28) with the bladder situated therebetween the two sheets (see Fig. 3). Kuiper is silent as to the bladder being physically joined to the outer sheet (note that Kuiper teaches the inner and outer sheets are connected to each other to form the bladder) and with the inner sheet not being physically joined to the bladder. However,

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Zablotsky teaches a similar inflatable compression device which includes an inner and outer sheet (Zablotsky 86 & 84 Fig. 9, respectively) in which an inflatable bladder (Zablotsky 116 Fig. 9) in which the inflatable bladder is physically joined to the facing surface of the outer sheet and not physically joined to the facing surface of the inner sheet (see Zablotsky Fig. 9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Kuiper device by replacing the bladder defined by the inner and outer sheets with the removable inflatable bladder physically attached to the outer sheet and not physically attached to the inner sheet as taught by Zablotsky in order to provide removability for the inflatable bladders for replacement or varying the configuration of the inflatable bladders in the compression device for enhanced therapeutic effects. The now modified Kuiper device is silent as to including a heating element. However, Detty teaches a compression sleeve device (see Detty col. 2 In. 15-19) which includes a heating element which is at least a substantial portion of the inner sheet and is electrically conductive material (Detty 42: see also Detty col. 5 In. 42-44 and col. 4 In. 53-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Kuiper device to include the heating elements as taught by Detty in order to provide an additional therapeutic effect to the user.

In regards to claim 27, the modified Kuiper device's heating element extends across at least a major portion of the inner sheet (see Detty col. 5 ln. 42-44), and includes electrically conductive material (see Detty col. 4 ln. 53-54).

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In regards to claim 28, the modified Kuiper device's heating element extends across the entirety of the inner sheet (see Detty col. 5 In. 42-44).

In regards to claim 29, the modified Kuiper device's outer sheet is formed of inextensible material (see Kuiper para. 0060 and para. 0066).

In regards to claim 30, the modified Kuiper device includes one or more locations at which the outer sheet is joined to the bladder spaced away from locations at which the outer sheet is joined to the inner sheet (see Zablotsky Fig. 9).

## Response to Arguments

 Applicant's arguments with respect to claims 11-12, 14-15, 17-25, and 27-31 have been considered but are moot in view of the new ground(s) of rejection.

The applicant's argument that claims 25 and 27-29 are compliant with USC 101 (page 8 of remarks) is not well-taken as a claim to a human body, or a portion of a human body is non-statutory subject matter.

#### Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents are considered to be pertinent art: Ben-Noon (6,010,471) to a body treatment apparatus, Kelly et al. (5,383,919) to a thermal therapy pad, and Rutt et al. (6,592,543) to an inflatable medical appliance.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/ Examiner, Art Unit 3771

/Justine R Yu/ Supervisory Patent Examiner, Art Unit 3771